

Status: July 14, 2023

§ 1 General

- (1) Berlin Cert Prüf- und Zertifizierstelle für Medizinprodukte GmbH (hereinafter referred to as Berlin Cert GmbH) provides the contractually agreed services to its contractual partner on the basis of and in application of these General Terms and Conditions (hereinafter referred to as GTC).

The contractual partner agrees to their validity and inclusion as an integral part of the concluded contract.

- (2) Terms and conditions of the contractual partner that contradict or deviate from these GTC are not recognized by Berlin Cert GmbH and do not become part of the contract even if Berlin Cert GmbH does not expressly object to them. A tacit acknowledgement of conflicting or deviating terms and conditions of the contractual partner is excluded.
- (3) The following terms and conditions shall apply to the entire contractually agreed service as well as to ancillary services rendered within the scope of the execution of the contract and other contractual ancillary obligations.
- (4) Amendments or collateral agreements to these GTCs require prior written agreement between Berlin Cert GmbH and the contractual partner in order to be valid. Deviating agreements and collateral agreements apply only to the respective individual contract.

§ 2 Scope

- (1) These GTC regulate the performance of the contractually agreed services in connection with the testing, evaluation, certification and assessment of management systems or medical devices with regard to safety, usability and quality on the basis of the statutory regulations, standards and technical provisions applicable to the respective management system or medical device.
- (2) For the performance of the contractually agreed services, the contractually agreed remuneration plus the statutory value added tax shall be charged at the rate applicable at the time of performance.
- (3) Incidental costs, such as shipping costs or travel expenses, are not included in the contractually agreed remuneration. Insofar as ancillary costs are incurred in connection with the provision of the contractually agreed services, these are to be reimbursed by the contractual partner against proof plus the statutory value added tax in the amount applicable at the time of performance

§ 3 Scope of services/period of Berlin Cert GmbH

- (1) For the scope of the service the contract concluded in text form between the contracting parties is decisive. Berlin Cert GmbH owes exclusively the contractually specified services, which are provided in compliance with the generally accepted rules of technology. It assumes no responsibility for the correctness of the laws, guidelines and standards on which the contracts are based.
- (2) The contractually agreed performance deadlines and dates are based on estimates of the scope of work and services by Berlin Cert GmbH based on the information provided by the contractual partner . Deadlines stated by Berlin Cert GmbH are non-binding, unless their binding nature is expressly agreed in text form.
- (3) Binding performance deadlines begin at the time agreed in the contract . Insofar as an advance payment has been contractually agreed or advance performance by the contractual partner has been agreed, the period shall not commence until the advance payment has been received or the advance performance has been fulfilled. The later point in time shall be decisive in each case.

§ 4 Obligations of the contracting party

- (1) The contractual partner is obliged to provide Berlin Cert GmbH free of charge with all objects, samples or documents concerning the subject matter of the contract, which are necessary for the provision of the contractually agreed service.
- (2) The Contractual Partner undertakes to provide Berlin Cert GmbH and the persons commissioned by it with further documents relating to the subject matter of the contract upon request within a reasonable period of time set by Berlin Cert GmbH or the persons commissioned by it.
- (3) Documents submitted to Berlin Cert GmbH will only be accepted in German or English.
- (4) The Contractual Partner undertakes to provide all necessary cooperation in due time and free of charge for Berlin Cert GmbH. In fulfilling its duties to cooperate, the contractual partner must ensure compliance with all applicable legal regulations, technical standards, safety regulations and accident prevention regulations.
- (5) The contracting party shall bear any additional expenses incurred due to the fact that contractually agreed services must be repeated or are delayed in whole or in part as a result of incorrect, incomplete or delayed provision of required items, samples or documents and other information for which the contracting party is responsible, or due to failure to cooperate or delayed cooperation. Even if a binding fixed or maximum price has been agreed upon, Berlin Cert GmbH is entitled to charge such additional expenses additionally. Berlin Cert GmbH shall invoice the additional expenses taking into account the actually incurred and proven additional time or material expenses; the calculation of the additional expenses shall be based on the remuneration rates for time and material expenses on which the contractual agreement is based.
- (6) If the contracting party discovers that a test sample certified by Berlin Cert GmbH has been or may be the cause of personal injury, property damage or other damage, it is obliged to inform Berlin Cert GmbH of this immediately in writing. In cases where the testing has been carried out by a testing laboratory other than Berlin Cert GmbH commissioned by the contractual partner and whose results have been taken over by Berlin Cert GmbH as a basis for the certification of the test sample, the contractual partner has to inform Berlin Cert GmbH immediately in writing, if he finds out that the results of the other testing laboratory on which the certification is based are completely or partly invalid, void or not valid.
- (7) The Contractual Partner undertakes to indemnify Berlin Cert GmbH, its managing directors, employees, officers and vicarious agents from all costs and expenses directly caused by
 - a) a violation of the provisions of these GTC,
 - b) an application of tested equipment or management systems in a manner inconsistent with the contractually agreed test,
 - c) a follow-up audit of the devices certified according to these regulations,
 - d) any damage-causing event that occurs during the testing of the equipment or
 - e) a breach of submission, cooperation and information obligations attributable to the contractual partner.
- (8) The Contractual Partner undertakes not to publish or reproduce the work results of Berlin Cert GmbH handed over to him, either in full or in part, without the written permission of Berlin Cert GmbH. Furthermore, the Contractual Partner undertakes not to use, quote or interpret the test results in an abusive, falsifying or misleading manner.

§ 5 Warranty / Liability

- (1) The warranty of Berlin Cert GmbH only covers the contractually agreed services. No warranty is given for the correctness and functioning of a test object including all assessed or tested parts, in particular for design, material selection and construction of the examined equipment, as far as these points are not explicitly subject of the contract.
- (2) As far as the Contractual Partner commissions Berlin Cert GmbH with the inspection of functionality, design, material selection and construction of a test item, Berlin Cert GmbH is liable for a proper inspection and appraisal of the test item according to the applicable legal regulations, standards and technical provisions.

Any further liability of Berlin Cert GmbH, in particular a warranty or other legal responsibility of Berlin Cert GmbH for the functionality or freedom from defects of the tested object towards purchasers, users or other third parties is not established by the test.

The warranty obligation and the legal responsibility for the functionality and freedom from defects of the tested object in relation to purchasers, users or other third parties rests exclusively with the contractual partner.

The Contractual Partner undertakes to indemnify Berlin Cert GmbH and its vicarious agents against all claims of third parties asserted against Berlin Cert GmbH due to lack of functionality or defects of a tested item; this does not apply insofar as the lack of functionality or the defect could have been detected by Berlin Cert GmbH during proper testing according to the applicable legal regulations, standards and technical provisions.

- (3) With regard to the services of testing, evaluation, certification and assessment of management systems or medical devices provided by Berlin Cert GmbH, the Parties agree that Berlin Cert GmbH does not owe any success or a specific result. Berlin Cert GmbH exclusively provides the contractually agreed service. The measures to be taken as a result of the service provided are the responsibility of the contract partner.
- (4) In case of non-performance by Berlin Cert GmbH, its obligation to perform under the contract shall continue to exist, unless the non-observance of the performance time leads to an impossibility of performance.
- (5) Complaints against the contractual provision of contractually agreed services are to be reported in writing to Berlin Cert GmbH by the Contractual Partner immediately after discovery, but at the latest within one year after handover of the report or certificate.
- (6) Spelling or grammatical errors as well as errors in the formatting of the text or in the layout in test reports can be corrected by Berlin Cert GmbH at any time and do not entitle the Contractual Partner to make complaints. In this case, the contractually owed service is considered to have been properly provided.
- (7) Berlin Cert GmbH is not liable in case of simple negligence of its organs, legal representatives, employees or other vicarious agents, as far as it does not concern a breach of essential contractual obligations.

Essential to the contract is the obligation to perform the contractually agreed service of testing, evaluating, certifying or assessing management systems or medical devices with regard to safety, usability and quality on the basis of the relevant statutory regulations, standards and technical provisions applicable to the respective management system or medical device.

- (8) In the event of a breach of essential contractual obligations, Berlin Cert GmbH's liability for damages is limited to damages that Berlin Cert GmbH foresaw as a possible consequence of a breach of obligation at the time of the conclusion of the contract or that it should have foreseen by exercising due care. Liability for indirect consequential damages, including consequential damages typical for this type of contract, is excluded.
- (9) These exclusions and limitations of liability do not apply to damages resulting from personal injury or damages caused by intentional or grossly negligent breach of duty by a legal representative or vicarious agent of Berlin Cert GmbH.
- (10) If claims for damages against Berlin Cert GmbH are excluded, this also applies to the personal liability of its vicarious agents.

- (11) The contracting party undertakes to indemnify Berlin Cert GmbH against claims for damages of any kind asserted by third parties against Berlin Cert GmbH due to improper, inadmissible or unauthorized use of a certificate or test report by the contracting party.

§ 6 Confidentiality

- (1) The parties undertake to treat all confidential information and business secrets of the respective other party which become known within the framework of the contractual relationship as strictly confidential, even beyond the duration of the business relationship, and to maintain secrecy about them. The parties undertake in particular not to make the confidential information available to third parties or to pass it on.
- (2) Copies may be made for the files of Berlin Cert GmbH of documents, drawings, plans, etc., which have been made available to Berlin Cert GmbH for inspection and which are of importance for the execution of the contract.
- (3) Disclosure of the confidential information is permitted to the extent that
- a) this is done with the prior written consent of the party affected by the disclosure, or
 - b) disclosure is made to the management or - on a need-to-know basis - to employees or professional secrecy holders (e.g. lawyers, auditors, tax consultants) bound to secrecy, to the designation and accreditation organizations commissioned by Berlin Cert GmbH within the scope of their monitoring activities, or to auditors of certification bodies, insofar as this is necessary for certification purposes;
 - c) Berlin Cert GmbH is required to do so under applicable law or in the context of proceedings before a governmental, judicial, regulatory or administrative authority or a securities exchange.
 - d) In the cases of letters b) and c), the disclosure may also be made without the written consent of the party affected by the disclosure; in such cases, the disclosing party shall be obliged to notify the party affected by the disclosure in text form of the intended disclosure and its purpose and to give the latter the opportunity to comment on whether and to what extent disclosure of the confidential information is permissible or what reasons prevent disclosure.
- (4) The obligation to maintain confidentiality shall not apply to confidential information that is publicly available or is made publicly available without violating any provisions of this Agreement.

§ 7 Copyrights

Unless otherwise contractually agreed, all copyrights to documents prepared by Berlin Cert GmbH, in particular expert opinions, audit results, calculations or presentations of any kind, remain with Berlin Cert GmbH.

§ 8 Complaints procedure

The Contractual Partner may lodge a complaint in writing if he is not satisfied with services or decisions of Berlin Cert GmbH.

The contract partner as well as the management and QMB of Berlin Cert GmbH will be informed immediately about the receipt of the complaint.

Complaints are handled by a complaints committee with the participation of the quality management representative of Berlin Cert GmbH.

The Appeals Committee shall decide on the appeal.

The decision shall be communicated to the contracting party in text form.

§ 9 Privacy

The personal data transmitted with the contact are processed electronically for the implementation of pre-contractual measures as well as for the fulfillment of the contract. Berlin Cert assures that this data will be used exclusively for the establishment, content or modification of the contractual relationship. Auditors, examiners, subject matter experts and environmental verifiers who provide auditing services on behalf of Berlin Cert are obligated in writing to comply with the legal data protection regulations.

Further information on the protection of personal data can be found in the current privacy policy of Berlin Cert GmbH at <https://www.berlincert.de/de/datenschutz>.

§ 10 Assignment

The contracting parties may assign rights and obligations under the contract in whole or in part with the prior consent of the other contracting party in text form.

§ 11 Internal Market Sales Tax Act

- (1) Berlin Cert GmbH uses the VAT ID DE 162977933 in the intra-community trade of goods.
- (2) The contracting party is obligated to provide the tax-relevant details of its name, address and VAT ID number without delay and without request, at the latest upon conclusion of the contract. He is obliged to inform Berlin Cert GmbH immediately of any change of his name, address and VAT ID number.

If a non-taxable service is treated as taxable due to deficiencies in the information of the name, address or VAT ID number, the Contractual Partner shall reimburse the tax payable by Berlin Cert GmbH.

- (3) If double taxation occurs - purchase tax in the buyer's country, sales tax in Germany - the buyer pays the excess tax back to Berlin Cert GmbH.

§ 12 Place of performance and jurisdiction, applicable law

- (1) The place of performance for all services to be rendered by Berlin Cert GmbH within the scope of the contractual agreement is Berlin.
- (2) The place of jurisdiction is agreed to be Berlin, Germany.
- (3) The exclusive application of the law valid in the Federal Republic of Germany is agreed. The application of the UN Convention on Contracts for the International Sale of Goods (CISG) is excluded.

§ 13 Terms of payment and prices

- (1) If the performance period is extended for a period of more than four months after the conclusion of the contract due to causes for which the contractual partner of Berlin Cert GmbH is responsible, the new price shall apply from the fifth month in the event of an increase in the published price in the meantime.
- (2) In the event that services are performed outside of Germany, the Contractual Partner must pay all direct or indirect national taxes and/or levies to authorities and/or corresponding local bodies and undertakes to provide Berlin Cert upon request with all necessary proof documents regarding the payment of such taxes and/or levies. In the case of cross-border transfers, the Customer shall bear the transaction fees incurred.
- (3) Berlin Cert GmbH is entitled to demand an advance payment from the Contractual Partner up to the amount of the remuneration owed according to the contract.

Berlin Cert is entitled to issue partial invoices. Partial invoices do not have to be designated as such; receipt of an invoice does not mean that Berlin Cert GmbH has thereby settled the order in full.

- (4) Unless expressly agreed otherwise, invoices shall be issued as electronic invoices and sent to the contracting party electronically.
- (5) The invoice amount is due for payment within 2 weeks after receipt of the invoice. In the event of later payment, interest at a rate of 9 percentage points above the prime rate will be charged for the outstanding invoice amount for the period between the due date of payment and receipt of the money.

The invoice amount is to be transferred to the account of Berlin Cert GmbH stated in the invoice by the due date.

- (6) Offsetting against or retention due to a counterclaim of the contractual partner is excluded, unless the counterclaim is undisputed or legally established.
- (7) If the client is in arrears with the payment of an invoice, Berlin Cert GmbH may terminate the contract for good cause if the contracting party fails to pay the due amount despite a reasonable payment deadline set for it.

The right of Berlin Cert GmbH to demand interest on arrears at the statutory rate or compensation for further damage caused by default from the Contractual Partner in the event of default in payment remains unaffected.

- (8) Sales tax shall be charged in the amount applicable at the time of performance of the contractual service in addition to the service prices and shall be shown separately.
- (9) Complaints about invoices must be made in text form within a preclusive period of 14 days after receipt of the invoice, stating the reasons.

After the expiry of the time limit for objections, the invoice shall be deemed approved.

§ 14 Deviating provisions

Deviations from these General Terms and Conditions of Business require written agreement in the contract concluded between the parties in order to be effective.

§ 15 Final provision

If individual provisions of these General Terms and Conditions should be invalid or unenforceable or if these General Terms and Conditions contain loopholes, this shall not affect the validity of the remaining provisions. In place of the invalid or unenforceable provision, the valid or enforceable provision that most closely approximates the economic intent and purpose of the invalid or unenforceable provision shall be deemed agreed.

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